



Certificate Number US19/81841351

# The management system of Rhythmlink International, LLC

1140 1st Street South, Columbia, SC, 29209, United States

Facility identification number : F001596

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



## MDSAP (ISO 13485:2016)

Australia:  
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]  
Brazil:  
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009  
Canada:  
Medical Devices Regulations – Part 1 SOR 98/282  
United States:  
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**See second page for the scope.**

The certificate is valid from  
Effective Date: 2022-01-11 until Expiry Date: 2025-01-10  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-08-30  
Issue 4. Certified since 2019-01-15

Authorised by L Henderson  
Business Manager



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MDSAP-M2

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The management system of

# RhythmLink International, LLC

## MDSAP (ISO 13485:2016)



Issue 4

Detailed scope

**Design, Development, Manufacture and Distribution of Sterile Subdermal Needle Electrodes, EEG Electrode Template, EEG Electrode Headset, Electrode Cable, EMG Electrodes, Stimulating Probes and Non-sterile Cutaneous Electrodes in the area of Electromyography (EMG), Electroencephalograph (EEG) and Nerve potential signals.**

Additional facilities

**1130 1st Street South, Unit B and C, Columbia, SC, 29209, United States**

